



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/521,730

01/20/2005

Robert John Noel

MCA-609 US

2258

25182 7590 02/13/2008  
MILLIPORE CORPORATION  
290 CONCORD ROAD  
BILLERICA, MA 01821

EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

02/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/521,730

Applicant(s)

NOEL, ROBERT JOHN

Examiner

David A. Saunders

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **AMENDMENT ENTRY**

Amendment of 11/19/07 has been entered. Claims 1-3 and 5-11 are pending. Claims 1-3 and 5-11 are under examination.

## **CORRECTIONS REGARDING PREVIOUS OFFICE ACTION**

The following corrections pertain to the previous Office action:

At page(s) 5, 7 lines from bottom, "1-2, 4 and 9" should have read as --1-2, 4, 6 and 9--.

At page(s) 5, 4 lines from bottom, "DePhillips" should have read as --Wu--.

At page(s) 6, line 1 "(both values shown in Fig 2)" should have read as --(see values of 72 and 173 shown in Table 1)--.

## **OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN**

The amendment has overcome previously stated issues as follows:

The objection to the specification.

The rejection of claim(s) 2, 7 and 8 under 35 USC 112, 2<sup>nd</sup> paragraph.

The prior art rejection of claim(s) 1-2, 5-7 and 9 based upon Scholz et al. The reference does not state the ligand density of any of the adsorbents studied. The adsorbents of this reference were prepared in the authors' own laboratory (pp 190-192). There is thus no standard reference which one could consult in order to determine what might be the inherent ligand density of any of the adsorbents.

The prior art rejection of claim(s) 1-3, 6 and 9 based upon DePhillips et al. It is noted that the Sulfopropyl adsorbents shown in Table 1 have an ionic exchange capacity outside of the range recited in amended claim 1. The carboxymethyl adsorbents shown in Table 1 have an ionic exchange capacity that overlaps the upper end the range recited in amended claim 1. It is taken that this overlap does not point out the instantly recited range with sufficient specificity to anticipate or render obvious the method of claim 1. See MPEP 2103.03, part II.

The prior art rejection of claim(s) 1-3 and 5-9 based upon Ramage et al, since the reference is silent about ligand density.

**MAINTAINED REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH**

Claims 1-3 And 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "in the absence of added ionic component that competitively binds the adsorbent" is indefinite, because one does not know if a) the "added ionic component" is one the competes with the "selected ionic component" for binding to the adsorbent, b) the "added ionic component" is one the competes with some unrecited undesired/non-selected ionic component for binding to the adsorbent, or both a) and b).

**MAINTAINED REJECTION(S) UNDER 35 USC 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al (Jour. Chromat. 1992).

The rejection of Claims 1-2, 4, 6 and 9 was explained in the action of 5/14/07.

Though dependent claim 6 was not listed as rejected, in the last full para. at page 5, claim 6 was indicated as being anticipated by the reference, in the first full para. of page 6.

Regarding new claims 10-11, it was previously noted that a carboxylate ligand density of 173  $\mu\text{mol/g}$  (see value of 173 in Table I) would correspond to a density of  $\sim 26$   $\mu\text{mol/ml}$ . This calculated value of  $\sim 26$   $\mu\text{mol/ml}$  is above "about 20" recited in claim 10 and is encompassed by "about 30" in claim 11.

Applicant has urged that the reference cannot be applied because Wu et al did not bind the ionic component (e.g. lysozyme) to the cation-exchange adsorbent "in the absence of an added second ionic component that competitively binds the adsorbent" (wherein the added second ionic component would be, for example a  $\text{Na}^+$  salt). The Office will maintain the rejection over this argument on two grounds.

1) While Wu et al show experiments in which there is an added second ionic component that competitively binds the adsorbent (e.g. in Table II, even the lowest ionic strength studied was 0.16, which was obtained by using a buffer mixture containing 25% B (Buffer B is 0.01 M Na Phos-0.2M Na Sulfate, as disclosed at p 8, col. 2), it is taken that then only common sense reading of the experiments shown in Figs. 1 and 2, in which "ion exchange capacity" was determined, is that Buffer B is 0%. Note that the legend to Fig. 1 refers to "phosphate buffer" rather than to any mixture of sodium phosphate and sodium sulfate. If Buffer B is not 0%, how the does one determine "ion exchange capacity" in the presence of an added second ionic component (i.e. sulfate) that competitively binds the adsorbent?

2) Even if the Wu et al reference did only show experiments in which there is an added second ionic component that competitively binds the adsorbent, the reference would still anticipate. This is because claim 1 can be read such that the recitation of "in the absence of an added second ionic component that competitively binds the adsorbent" need not refer to the conditions of the claimed method but, rather, as a mere description of how the ionic adsorbent would act under conditions in which there is no added second ionic component that competitively binds the adsorbent.

**NEW REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH**

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, it is not clear if the one of the "two ionic components" that is not bound to the adsorbent is the same as the "second ionic component" of base claim 1.

**NEW REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH**

Claims 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In each of claims 10-11, all recitations of

"about" constitute new matter, since there are no corresponding recitations of "about" at specification page 3, line 17.

## **FINALITY**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

## **CONTACTS**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

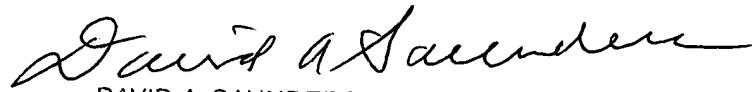
Application/Control Number:  
10/521,730  
Art Unit: 1644

Page 7

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 2/5/08 DAS

  
DAVID A. SAUNDERS  
PRIMARY EXAMINER